

REMARKS

The pending Office Action addresses claims 1, 3, 4, 6-9, and 11-25¹, allowing claim 25 and rejecting claims 1, 3, 4, 6-9, and 11-24. By this response, claims 1, 17, and 21-24 are amended. Reconsideration and allowance are requested in light of the amendments and the following remarks.

Amendments to the Claims

Applicants amend claims 1, 17, and 21-24 to clarify that the maneuverable apparatus includes a tubular deflection member that is capable of *longitudinal manipulation* relative to an elongate member. Support for these amendments can be found throughout the specification at least at page 6, lines 1-6.

No new matter is added.

Claims 1, 3, 4, 6-9, and 11-25 are now pending.

Rejections of Claims 1, 3, 4, 6-9, 11, 12, 15, 16, and 23

The Examiner maintains his rejection of claims 1, 3, 4, 6-9, 11, 12, 15, 16, and 23 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,104,392 of Kittrell et al. in combination with U.S. Patent No. 5,306,245 of Heaven. Applicants disagree with the Examiner's rejections.

Applicants' invention is directed to a unique device and method for steering a catheter into body tissues, e.g., chambers of the heart, for medical purposes such as tissue destruction. As a result of its directional capabilities, the device limits the delivered energy to the precise preselected site, thereby minimizing trauma to adjacent surrounding tissue and achieving an enhanced medical benefit. The present invention is a catheter-like device for positioning a treatment assembly in the area or organ selected for medical treatment and includes one or more deflection members mounted within the catheter for positioning catheter within the preselected body cavity.

¹ In the Office Action, the Examiner states that claims 1, 3, 4, 6-9, and 11-24 are pending, however fails to note that claim 25 is also pending.

The present invention is based, at least in part, on the discovery that attachment of a polymeric, tubing like deflection member to the distal end of a flexible elongate member, e.g. a catheter, provides a means to bend, distort, or deform the flexible elongate member to a desired position. In particular, independent claims 1 and 23 recite devices that include a tubular deflection member that is capable of *longitudinal manipulation* relative to an *elongate member*. As a consequence of this maneuverability, an energy beam can be directed onto/into a specific target site, e.g., an anatomically important region, for treatment.

At the outset, Applicants reiterate their position that one having ordinary skill in the art would have no motivation to combine Kittrell and Heaven for the reasons recited in the prior responses. Further, the amended claims distinguish over Kittrell and Heaven because neither reference teaches a device that includes a tubular deflection member that is capable of *longitudinal manipulation* relative to an *elongate member*.

In the Office Action the Examiner states that “Kittrell et al teach a device as claimed except for the particular deflection member.” However, and contrary to the assertions of the Examiner, Heaven does not remedy the deficiencies of Kittrell. Heaven teaches a uniplanar medical steering device that includes a tubular member having a cut-out (or hinge) formed in a wall thereof. The device also includes a sheath that covers at least the cut-out portion of the tubular member, and a control wire. In use, movement of the control wire causes one end of the tubular member to move back and forth in a plane relative to the other (and opposite) end of the tubular member while the sheath remains in place to cover the portion of the tubular member at the cut out. Thus, the tubular member is only capable of moving relative to *itself*, and manipulation of the deflection member does not cause the deflection member to move longitudinally relative to any type of *elongate member*, as required by Applicants’ claims.

Accordingly, Kittrell in combination with Heaven does not teach or even suggest the recitations of claims 1, 3, 4, 6-9, 11, 12, 15, 16, and 23, and one having ordinary skill in the art would have no motivation to combine Kittrell with Heaven. Claims 1, 3, 4, 6-9, 11, 12, 15, 16, and 23 therefore represent allowable subject matter, and allowance thereof is respectfully requested.

Rejections of Claims 17-21

The Examiner also rejects claims 17-21 pursuant to 35 U.S.C. § 103(a) as being obvious over Heaven in combination with Kittrell. Applicants disagree with the Examiner's rejections.

At the outset, Applicants reiterate their position that one having ordinary skill in the art would have no motivation to combine Heaven and Kittrell for the reasons recited in the prior responses. Further, and as noted above, the amended claims distinguish over Heaven and Kittrell because neither reference teaches a method that includes introducing a deflection member that is capable of longitudinal manipulation relative to an elongate member.

Accordingly, claims 17-21 distinguish over Heaven in combination with Kittrell and represent allowable subject matter, and allowance thereof is respectfully requested.

Rejections of Claims 13 and 14

The Examiner also rejects claims 13 and 14 pursuant to 35 U.S.C. § 103(a) as being obvious over Kittrell in combination with Heaven, and further in view of U.S. Patent No. 5,129,895 to Vassiliadis et al. Applicants disagree with the Examiner's rejections.

At the outset, Applicants reiterate the position that neither Kittrell nor Heaven teach or even suggest a deflection member that is capable of longitudinal manipulation relative to an elongate member. Kittrell and Heaven also do not teach or even suggest a layer of reflective material affixed to the distal end region of the elongate member.

Vassiliadis does not remedy the deficiencies of Kittrell and Heaven because Vassiliadis teaches a reflective material that is located in an entirely different place, and has an entirely different purpose than that recited by Applicants. Further, Applicants reiterate that one having ordinary skill in the art would have no motivation to combine Kittrell, Heaven, and Vassiliadis because Vassiliadis is directed to an entirely different surgical procedure than Kittrell and Heaven. In particular, Vassiliadis is directed towards *performing a sclerostomy* (forming a small hole in the sclera of an eye) as a treatment of glaucoma, and Kittrell and Heaven are directed towards intravascular laser treatment of atherosclerotic disease or conventional arthroscopic or laparoscopic procedures.

Accordingly, Kittrell, Heaven, and Vassiliadis do not teach or even suggest the recitations of claims 13 and 14, and one having ordinary skill in the art would have no motivation to combine Kittrell, Heaven, and Vassiliadis. Claims 13 and 14 therefore represent allowable subject matter, and allowance thereof is respectfully requested.

Rejections of Claims 22 and 24

Additionally, the Examiner rejects claims 22 and 24 pursuant to 35 U.S.C. § 103(a) as being obvious over Kittrell in combination with Heaven, and further in view of U.S. Patent No. 4,985,028 to Isner et al. Applicants disagree with the Examiner's rejections.

At the outset, Applicants reiterate the position that neither Kittrell nor Heaven teach or even suggest introducing a deflection member that is capable of longitudinal manipulation relative to an elongate member. Kittrell and Heaven also do not teach or even suggest positioning a slidable conductor through the lumen of the elongate member proximate to the atrial tissue site.

The disclosure of Isner does not remedy the deficiencies of Kittrell and Heaven because nowhere does Isner teach or suggest any type of slidable conductor. Further, Applicants reiterate that one having ordinary skill in the art would have no motivation to combine Kittrell, Heaven, and Isner because the teachings of Isner are the exact opposite as those of Kittrell and Heaven. In particular, while the teachings of both Kittrell and Heaven are directed towards *movement* of the device, Isner teaches sliding the distal end of a catheter into a patient's heart, and moving a fixation wire proximally to the distal end of the catheter to *prevent movement* of the catheter during use and provide rigidity to the catheter to maintain the portion of the distal tip during use.

Accordingly, Kittrell, Heaven, and Isner do not teach or even suggest the recitations of claims 22 and 24, and one having skill in the art would have no motivation to combine Kittrell, Heaven, and Isner. Claims 22 and 24 therefore represent allowable subject matter, and allowance thereof is respectfully requested.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is kindly requested to telephone the undersigned representative in the event that the amendments do not place this case in condition for allowance or if a telephone interview can otherwise expedite the prosecution of this application.

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Respectfully submitted,

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